Iowa Community-Based Screening Services Procedures Manual

2014

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1. General Information - *About Iowa Community-Based Screening Services (CBSS)*

Iowa Community-Based Screening Services (CBSS) (formerly known as the Iowa Infertility Prevention Project) is a collaborative project between the **Family Planning Council of Iowa (FPCI), the Iowa Department of Public Health's (IDPH) Family Planning and STD Programs, and the State Hygienic Laboratory at the University of Iowa (SHL)**. Funded by the Centers for Disease Control and Prevention (CDC), testing and treatment for chlamydia and gonorrhea is done in clinic sites across the state. Data collection is an important part of the CBSS and is used on a state and local basis examine STD occurrence and trends, guide prevention and other programmatic priorities, and secure funding.

The Manual

The purpose of this manual is to provide clinic staff at the CBSS provider sites with a self-study guide to familiarize themselves with the purpose and procedures of the program. Upon receipt, this guide should be read and reviewed by all clinic staff involved with the CBSS. All new employees involved with the program should review the manual within one month of hire.

After reviewing the manual, the clinicians and other staff should then take the post-test located on page 29. This test and registration form should be returned to the CBSS Coordinator and will serve as proof for certification within the CBSS. The survey may also be taken on Survey Monkey.

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Importance of Detecting *Chlamydia trachomatis and Neisseria gonorrhoeae

Chlamydia is the most common bacterial sexually transmitted disease in the United States with gonorrhea being the second most common. The wider availability of affordable, cost-effective laboratory diagnostic tests for the presence of *Chlamydia trachomatis and Neisseria gonorrhoeae* has allowed further exploration of the broad spectrum of disease caused by these organisms.

In 2011, there were 1,412,791 cases of chlamydia and 321,849 cases of gonorrhea reported to the CDC.*

- 70% of chlamydial infections in women are asymptomatic, as are 50% of the gonorrhea infections.
- Chlamydia and Gonorrhea rates are highest in adolescents and young adults between the ages of 15 – 24.
- CDC estimates that undiagnosed and untreated STDs cause at least 24,000 women a year to become infertile.
- Untreated chlamydia and gonorrhea can also lead to epididymitis in men.
- Ectopic pregnancy is the leading cause of the first–trimester deaths in the U. S.
- *C. trachomatis* can cause neonatal pneumonia. Both *C. trachomatis* and *N. gonorrhoeae* can cause neonatal conjunctivitis.
- *C. trachomatis* and *N. gonorrhoeae* increases a woman's risk of acquiring HIV, if exposed to the virus.
- Gonorrhea is caused by *Neisseria gonorrhoeae*, which is gram-negative diplococcus bacterium.
- The Gonococcal Isolate Surveillance Report (GISP) continues to show decreasing susceptibility of the cephalosporins to *N. Gonorrhoeae*.

*CDC Fact Sheet, STD Trends in the U.S., 2011

Chlamydia and Gonorrhea testing at SHL

Nucleic acid amplified tests (NAATs) are recommended for the detection of reproductive tract infections caused by *C. trachomatis* and *N. gonorrhoeae* in men and women, with or without symptoms. According to CDC, optimal specimen types for NAATs are first catch urine from men and vaginal swabs from women.

At SHL, chlamydia and gonorrhea testing is performed using the Gen-Probe APTIMA Combo 2 Assay, which is a NAAT.

The Gen-Probe APTIMA Combo 2 Assay is FDA-approved for the testing of female endocervical and vaginal swabs, male urethral swabs, as well as male/female urine specimens. SHL has validated the APTIMA Combo 2 for use with oropharyngeal and rectal specimens.

The sensitivity of the Gen-Probe APTIMA Combo 2 Assay is greater than that of culture or the EIA assays for the detection of chlamydia and gonorrhea.

Test Performance Characteristics

There is no perfect test. Testing in low-prevalence populations may result in some false-positive results. Positive test results in a low-prevalence population should be interpreted carefully in conjunction with clinical signs and symptoms, client risk profile, and other findings with the understanding that a likelihood of a false-positive test may be higher than a true positive.

Definitions:

Sensitivity – The probability of a positive test result given the presence of disease. How good is the test at detecting infection in those who have the disease?

Specificity – The probability of a negative test result given the absence of the disease. How good is the test at calling uninfected people negative?

Predictive Value – The probability of the presence or absence of disease given the results of the test. Positive Predictive Value (PPV) is the probability of disease in a client with a positive result. Negative Predictive Value (NPV) is the probability of not having the disease when the test result is negative. How predictive is the result for that particular client? This is determined by the sensitivity and specificity of the test, and the prevalence rate of disease in the population testing.

Prevalence Rate – The number of cases of illness existing at a given time divided by the population at risk.

The APTIMA Combo 2 *C. trachomatis* sensitivity and specificity charts, the *N. gonorrhoeae* charts, and the Positive and Negative Predictive Values by prevalence rates and specimen sources can be found in Appendix A.

Enrollment in CBSS

All clinics must be approved for participation in the program. CBSS clinics include family planning, STD, or other agencies targeting disproportionately impacted populations or high morbidity areas. Requests will be considered based on funding availability, population served, and geographic location.

Agencies must sign a Memorandum of Agreement (MOA) with the CBSS to participate. The MOA is intended to provide a written understanding for the expectations of IDPH, CBSS, and the participating clinics. It is not a contract; however, but will be signed by the CBSS Administrator, IDPH, and the participating agency program director or manager.

Quality Assurance

CBSS recommends methods and sets standards for assuring quality and includes the following identified elements:

a. Desk monitoring;
b. Facility-specific assessments; and
c. Treatment/partner services

Considering these methods, the following is the Quality Assurance Plan for the CBSS:

Desk Monitoring – This is carried out through analysis of printed reports for the purpose of identifying trends and issues arising.

Rejected Specimens

1. Specimens are monitored as they are submitted to SHL and facilities are notified immediately of specimens that cannot be processed. The SHL establishes guidelines for specimen rejection based on the assay package insert and/or the regulator specifications.
2. The SHL will provide monthly and quarterly reports to the CBSS Coordinator that includes all specimens that were found to be unsuitable for testing and the clinics where they originated. A quarterly analysis of the rejected specimens and the reasons for rejection will be reported to each facility. (A list of rejection criteria can be found on pages 18-19.) Contact will be made with any facility with a higher percentage of rejected specimens than the state average for that quarter. Contact will be in the form of a letter. If no improvement is shown in the next quarter, a phone call will be made by the CBSS Coordinator to determine the causes and corrective action needed to be taken, such as on-site training.

Out of Criteria Specimens

Data from the lab requisition forms for each clinic will be reviewed by laboratory staff for birth date, plus the other information that relates to testing such as insurance status, signs and clinical impressions, symptoms, and risk history. Specimens from clients that do not fit the CBSS screening criteria will be rejected. If data are incomplete, clinics will be notified to obtain missing information as time allows. Clinics receive timely written notification of the rejection.

Data Collection/Accuracy

The CBSS Coordinator audits the test request forms for appropriate and accurate data collection. The lab form is the only means for data collection and complete data collection is necessary for effective program operation. Once a month, the CBSS Coordinator receives a spreadsheet from SHL with the data for each specimen submitted. Data are reviewed for incomplete data fields. A field left blank in an excess of five times in one month is considered above the state standard and the clinic submitting the specimen/data will be contacted by letter to advise them of the problem. Clinics receiving written notification for three consecutive months will be notified by phone by the CBSS Coordinator to help solve the data issues.

Quarterly Reports – Data Analysis

Data collected from test request forms is compiled to create the CBSS quarterly and year-end reports. These reports contain the total number of specimens submitted, total and percent positive for chlamydia and gonorrhea, and other data related to fields reported to the CBSS. The CBSS Coordinator will provide a yearly data analysis for the CBSS and each participating provider.

Facility Assessments – Site Visits

On an annual basis, the CBSS Coordinator will monitor a minimum of 20% of the current CBSS facilities during an in-person site visit in relation to the four elements from the Iowa Quality Assurance Plan. For most agencies, this will mean a routine site visit every three years. However, a visit may be done sooner if there is new staff or issues related to one of the quality assurance elements listed. The four elements that will be covered during the visit include:

1. Specimen Collection and Submission
2. Screening Criteria
3. Data Collection and Accuracy
4. Client/Partner Treatment and Education

CBSS providers must be available for site visits scheduled in advance during the clinic's regular business hours. Site visits typically last between 60 to 90 minutes and are informal in nature. The site visit provides an opportunity to ensure the clinic is not encountering any difficulties and to provide technical assistance when needed.

During site visits, the CBSS Coordinator will complete the Facility Services Assessment (FSA) form, as required by the Iowa QA Plan.

In addition to the FSA, the CBSS Coordinator may also (depending on clinic type) perform a medical record (chart) review. If a chart review is done, the CBSS Coordinator will specify the charts to pull, as well as a number of random charts.

Within seven days from the date of the site visit, the CBSS Coordinator will notify (by letter) the findings of the visit along with any issues needing corrective action or follow-up. A copy of the FSA and chart review, if applicable, will also be mailed.

Laboratory Quality Assurance

The SHL has been inspected and licensed under CLIA by the Health Care Facilities Administration.

CBSS Screening for Chlamydia and Gonorrhea

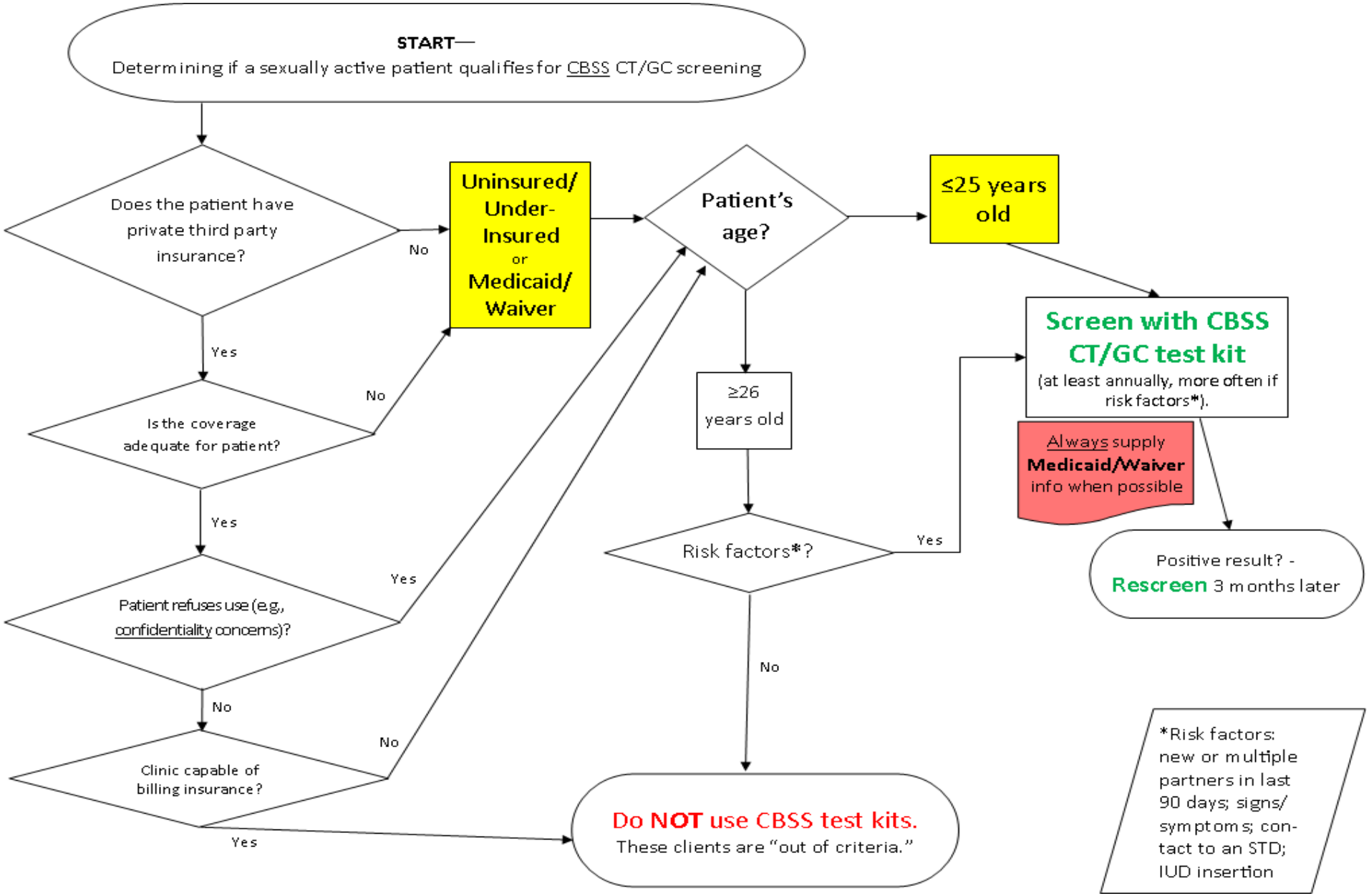
Screening is commonly defined as "testing in asymptomatic populations." Because of the frequent asymptomatic nature of chlamydial infections, screening becomes essential to controlling disease incidence and preventing potential complications. Economically, it is not possible to screen everyone; therefore, individual regions and states attempt to find the best criteria for their area based on CDC guidelines, published studies, and local prevalence data.

The CDC recommends annual chlamydia screening for all sexually-active women who are 25 years of age and younger. In addition they recommend rescreening women, regardless of age, with a previous positive test. According to their guidelines "Repeat infections confer an elevated risk for PID and other complications when compared with the initial infection. Therefore, recently infected women are a major priority for a repeat test for *C. trachomatis."* Clinicians should advise all women with CT/GC infection to be rescreened approximately three to four months after treatment.

Recent data suggest that screening sexually-active adolescent and young males for chlamydia are cost-effective and that a relatively high percentage of positivity is found in certain clinic settings. http://ncc.prevent.org/products/committee-products/file/EC_July-2013.pdf Recommendations against routine screening of young men are based upon an assumption of a positivity rate of less than five percent, in which case screening is not cost-effective. However, recent studies indicate a much higher positivity rate among young males attending family planning clinics, even when controlling for variables such as signs/symptoms and known exposure to chlamydia. A likely contributing factor is the migration of males from traditional STD clinics to family planning clinics due to the reduction of hours and closing of many stand-alone STD clinics. Local data affirm similar circumstances for Iowa. For these reasons, the CBSS program does recommend routine screening of sexually-active males 25 years of age and younger.

CBSS screening criteria are the same for females and males, including gay men and other men who have sex with men (MSM). The screening criteria generally refer to urogenital specimens. However, supplemental guidelines have been developed for oropharyngeal and rectal specimens based upon exposure and risk history. Regardless of gender, sexual orientation, or specimen type, the determination of whether an individual qualifies for screening using CBSS test kits must first be determined using the criteria of insurance status, age, and risk factors. (The included flow chart should be used to make this determination first.) The CBSS screening criteria are used for both chlamydia and gonorrhea testing. The criteria are based on a combination of recommendations (e.g., CDC) and local data. They focus on young age as the primary risk indicator. Other risk factors include new or multiple partners in the last 90 days, reported symptoms, and observed clinic findings at the time of the exam.

Specimens not meeting the screening criteria will be rejected. Clinics will be notified and may report additional information to justify testing of the specimen.



Community-Based Screening Services - Current Screening Criteria

Insurance Status

CBSS test kits must be prioritized for individuals who cannot obtain chlamydia and gonorrhea testing because it is cost prohibitive (e.g., lack of or inadequate insurance coverage.) This is the first criterion, before any consideration of risk (e.g. age) is taken into account. Please see the preceding flow chart for guidance on making this determination. Due to limited resources if the cost of testing can be covered by other means (e.g. private insurance) CBSS test kits must not be used. Exceptions will be made for clients requiring confidential services and testing.

Women and Men

Specimen collection for women may be done using a vaginal swab (self-collected or clinician-collected, if client is over 16 and not pregnant), a cervical swab, or a urine kit. Use of a urine collection kit in an outreach location must have prior approval from the CBSS Coordinator. Specimen collection for men may be done with a urine collection kit or urethral swab.

All Clinic Types

Women and Men ≤ 25 years of age:

- Screen all individuals ≤ 25 years of age annually
  - Screen all women ≤ 25 prior to IUD insertion, as indicated
- At an exam within 12 months of a negative chlamydia/gonorrhea test, screen ONLY if an individual has one or more of the following:
  - New or multiple partners in the last 90 days
  - Reported symptoms consistent with chlamydia or gonorrhea
  - Observed clinical signs consistent with chlamydia, gonorrhea or PID
  - Contact to an STD
  - IUD insertion (women)

Women and Men ≥ 26:

- Test all individuals 26 years of age and older if they have one or more of the following:
  - New or multiple partners in the last 90 days
  - Reported symptoms consistent with chlamydia or gonorrhea
  - Observed clinical signs consistent with chlamydia, gonorrhea or PID
  - Contact to an STD
  - IUD insertion (women)

Rescreen

- Rescreen all individuals, regardless of age, if they have tested positive for chlamydia or gonorrhea in the last 3 to 4 months. (This is a check for new or re-infection, not a test of cure.)

In order to determine whether oropharyngeal or rectal screening for gonorrhea or chlamydia is appropriate, see Appendix D. Please note that the above criteria must still be met regardless of specimen type (urogenital, oropharyngeal, or rectal).

2. Data Collection, Specimen Collection, Packaging, and Transport Procedures

Explanation of Data Collection

Data for the CBSS is submitted on the test request form that accompanies the specimen to SHL. It is vital that all fields are complete on every form, every time.

Social Security Number and/or a clinic client identification number are the only optional fields. ALL OTHERS ARE REQUIRED. Missing data in the fields will be tracked and clinics notified of these infractions. Remember to print clearly.

Explanation of Data Fields on the Test Request Form

Site of Collection

- Check only one choice by marking the box that identifies the site from which the specimen was taken (i.e., cervix, oropharyngeal, rectal, urethral, urine, and vaginal). Failure to do so will delay test results.

Date of Specimen Collection

- Please write in the date the specimen was collected. This information is critical. The final report will indicate if the date has been omitted and will request that the clinic notify the laboratory with the date.

Client Name

- Please ensure that the name on the test request form and the name on the specimen collection tube are an exact match; otherwise, the laboratory will reject the specimen. If there is no name on the specimen tube, it will be rejected.

Birth Date

- The date the client was born. Use the format of two-digit month, two-digit day, and four-digit year (e.g., 01/02/2010). If the date is not supplied the clinic will be contacted for this information.

Social Security Number

- This information is optional. It is not required by the CBSS for data collection purposes. The SHL uses this information for making definite client identification. If your clinic uses this number for identification purposes, please record it on the test request form.

Address

- SHL and the state STD Prevention Program use the address for further identification of the client in the instance of a positive test. The client's address may be used to determine the exact geographic distribution of disease trends.

City of Residence

- This field is used to determine the county of the client's residence. Write out the client's home city and state on the line provided.

Phone Number

- This information is collected by SHL on all test request forms. It is used for client notification by the Disease Prevention Specialist (DPS) only in the instance of a disease investigation resulting from a positive test.

Gender

- Indicate male or female by checking "M" for male or "F" for female. Determination of sex is made by observation or the medical record.

Race/Ethnicity

The categories for reporting race and ethnicity for the CBSS conform to the Office of Management and Budget (OMB) 1997 Revision to the Standard for the Classification of Federal Data on Race and Ethnicity. If this information is not already included in the client's medical record, the information should be collected by self-identification by the client. The client is now able to self-identify or self-report more than one of five races categories. Those marking more than one race will be collapsed into "More than one race reported" category in the final state and regional data. Both a racial and ethnic group must be marked on every form.

Race

- White: Includes persons of European descent, the Middle East, or North Africa
- Black: Includes persons having origins in any of the black racial groups of Africa
- American Indian or Alaskan Native: Includes persons having origins in any of the Indian peoples in North or South America (including Central America), and who maintains tribal affiliation or community attachment; Alaskan Indian, Eskimo, and Aleut are also included.
- Asian: Indicates persons having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Viet Nam.
- Native Hawaiian or Other Pacific Islander: Includes persons having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- Unknown: If the client does not know or does not wish to identify race.

Ethnicity

- Hispanic: Indicates persons having origins of Cuba, Mexico, Puerto Rico, South or Central America, or other Spanish culture or origin, regardless of race. The term, "Spanish origin", can be used in addition to "Hispanic" or "Latino".
- Non-Hispanic: Includes all other persons.
- Unknown: If the client does not know or does not wish to identify ethnicity.

Client Identification Number

- This is the clinic's identification number for the client, if your clinic uses a number other than Social Security Number.
- If you clinic does not use a client identifier, it can be left blank.

Clinician

- You must enter the clinician's full name.

Reason for Visit (Check only one)

- FP/Comprehensive: The client is attending the screening site primarily for routine services (i.e., initial/ annual or contraceptive visits for family planning services or other comprehensive health services).
- STD Screening: The client is attending the screening site primarily for STD services.
- Prenatal: This field is used by the clinics designated for testing prenatal clients by the CBSS. The client is attending the screening site primarily for prenatal services.
- Rescreen: All clients testing positive for chlamydia should be retested 3 to 4 months after treatment. This is not a "test of cure"; it is a check for re-infection. No testing should be performed until at least 3-4 weeks following the completion of treatment.
- Pre -IUD: The client is screened prior to insertion of an intrauterine device.

Risk History (Check all that apply)

- New Partner (last 90 days): Client reports a new sexual partner in the last 90 days.
- Multiple Partners (last 90 days): Client reports more than one sexual partner in the last 90 days or the client reports having a partner with multiple partners in the last 90 days.
- Contact to STD: Client reports having sexual contact with someone that has been diagnosed with any sexually transmitted disease in the last year.
- MSM: Male client reports he has engaged in sexual contact with other men in the last year.
- None: Client does not report any of the above; if this field is checked you may not check another field within this section.

Symptoms

- The client reports that he or she has (Yes) or does not have (No) symptoms. (e.g., itching, burning, discharge, pain with intercourse, etc.)

Signs/Clinical Impressions (Check all that apply)

- Cervicitis/Mucopurulent Cervicitis: An infection of the cervix; symptoms may include mucopurulent vaginal discharge and inflammation. Mucopurulent Cervicitis (MPC) is the presence of endocervical mucopus, which give yellow or green discoloration to an endocervical swab inserted into the os. It is defined as any of the following:
    - Edema, erythema, or follicle-like lesions in an area of ectopy (the extension of columnar epithelium onto the ectocervix), or
    - The presence of cervical mucus with ten or more polymorphonnuclear leukocytes per x 1000 microscopic field.
- Cervical Friability: Inflammation of the cervix; the client may report post-coital bleeding, or there may be bleeding when the swab touches the cervix.
- PID Suspicion: A diagnosis of PID (Pelvic Inflammatory Disease) is usually based on clinical findings, which is imprecise. The following are minimum criteria when no other cause can be identified:
    - Lower abdominal tenderness
    - Adnexal tenderness
    - Cervical motion tenderness
- Urethritis: An inflammation of the urethra characterized by the discharge of mucopurulent or purulent material, by burning during urination, or urethral itching.
- No Exam performed: Mark this field when collecting a urine or vaginal specimen and there was no physical examination.
- None of the above: A normal exam or an exam that does not include any of the above CT/GC related signs/clinical impressions.
    - Any other clinical impressions should not be considered when completing this field.

Insurance status (Check only one)

- Uninsured: the patient is not covered by any insurance, public or private
- Underinsured: the patient has insurance but it is inadequate or insufficient to cover their health care needs, such as STD testing
- Insured, patient refuses to use: the patient may refuse to use their insurance due to reasons to protect confidentiality
- Insured, clinic incapable of processing insurance: the provider site does not have the capacity to bill or process the patient's insurance **or** this is a facility that would not routinely bill for this service (correctional facilities, school-based clinics, etc.).
- Medicaid/Waiver information supplied: the patient has Medicaid or the Family Planning Waiver and the information is provided on the test request form.

Medicaid/Iowa Family Planning Network Information (IFPN)
Required Information

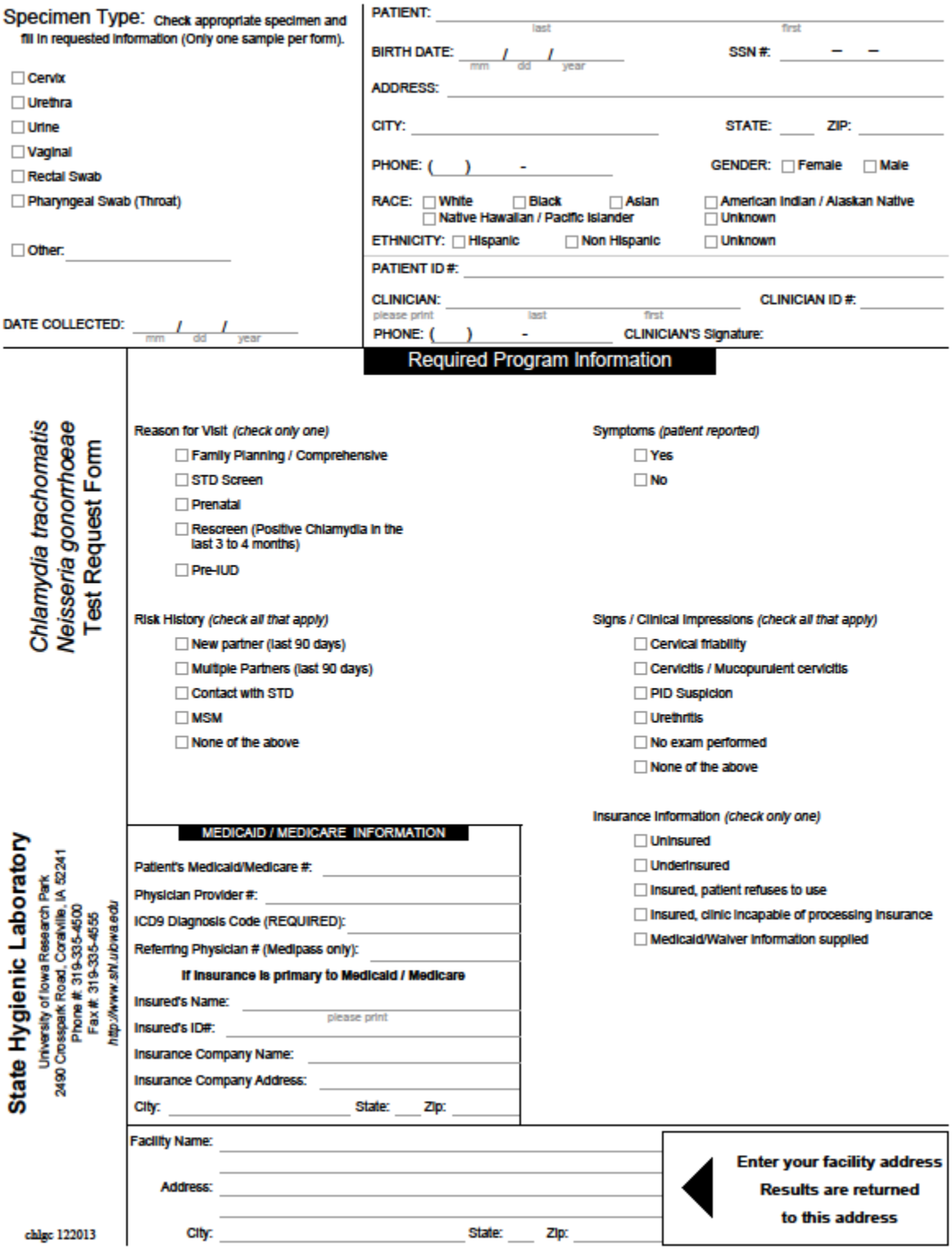
- **Client Medicaid, Medicaid HMO or Iowa Family Planning Waiver Number**
- **ICD9 Code**

- Please complete this information if the client has a Medicaid, Medicaid HMO or the Iowa Family Planning Network number.
    - IFPN information should be reported only if the chlamydia/gonorrhea test was part of a full contraceptive visit.
- If a client is covered by Meridian, it is considered Medicaid and the lab can bill. Please write in "Meridian" next to the patient's Medicaid # on the test request form.
- Be sure to provide the client's ICD-9 code, especially in the case of the IFPN. Without it, the lab's requests are denied as the processing of the specimen must be linked to the service provided. (*Please Note: Codes will change to ICD-10 in October 2014. New coding will be necessary at that time and you will be notified.*)

  Possible codes at this time are as follows:
    - IFPN Clients
        - V25.01 – related to the prescription of oral contraceptives
        - V25.02 – initiation of other contraceptive measures
        - V25.09 – other family planning advice
        - V25.40 – contraceptive surveillance unspecified
        - V25.41 - contraceptive pill
        - V25.49 – other contraceptive method
    - Medicaid Clients
        - V73.88 – special screening examination for other specified chlamydial disease
        - V74.5 – screening examination for venereal disease

- If you do not have a client's IFPN number at the time of submitting the specimen you should do so when that information is available:
    - Preferred method would be to fax a copy of the DHS Notice of Decision that will provide lab staff with the client name and client #. The lab staff can then look up the specimen for the rest of the information.
    - If this form is not available or you prefer not to send it, then fax the assigned number along with the client name, your clinic name, and if possible, the SHL lab number for that client.
    - Submit the information to John Negley at SHL. His fax number is 319-335-4171.
    - Do not email this information. Additional questions can be directed to John at 319-335-4442.

A sample SHL test request form follows on the next page.



Specimen Type: Check appropriate specimen and fill in requested information (Only one sample per form).

- ☐ Cervix
- ☐ Urethra
- ☐ Urine
- ☐ Vaginal
- ☐ Rectal Swab
- ☐ Pharyngeal Swab (Throat)
- ☐ Other: _____

DATE COLLECTED: ___/___/___ (mm dd year)

PATIENT: _____ (last) _____ (first)

BIRTH DATE: ___/___/___ (mm dd year) SSN #: ___ – ___ – _____

ADDRESS: _____

CITY: _____ STATE: ____ ZIP: _____

PHONE: (___) _____ - _____ GENDER: ☐ Female ☐ Male

RACE: ☐ White ☐ Black ☐ Asian ☐ American Indian / Alaskan Native ☐ Native Hawaiian / Pacific Islander ☐ Unknown

ETHNICITY: ☐ Hispanic ☐ Non Hispanic ☐ Unknown

PATIENT ID #: _____

CLINICIAN: _____ (please print last first) CLINICIAN ID #: _____

PHONE: (___) _____ - _____ CLINICIAN'S Signature:

Chlamydia trachomatis
Neisseria gonorrhoeae
Test Request Form

Required Program Information

Reason for Visit *(check only one)*

- ☐ Family Planning / Comprehensive
- ☐ STD Screen
- ☐ Prenatal
- ☐ Rescreen (Positive Chlamydia in the last 3 to 4 months)
- ☐ Pre-IUD

Symptoms *(patient reported)*

- ☐ Yes
- ☐ No

Risk History *(check all that apply)*

- ☐ New partner (last 90 days)
- ☐ Multiple Partners (last 90 days)
- ☐ Contact with STD
- ☐ MSM
- ☐ None of the above

Signs / Clinical Impressions *(check all that apply)*

- ☐ Cervical friability
- ☐ Cervicitis / Mucopurulent cervicitis
- ☐ PID Suspicion
- ☐ Urethritis
- ☐ No exam performed
- ☐ None of the above

MEDICAID / MEDICARE INFORMATION

Patient's Medicaid/Medicare #: _____

Physician Provider #: _____

ICD9 Diagnosis Code (REQUIRED): _____

Referring Physician # (Medipass only): _____

If insurance is primary to Medicaid / Medicare

Insured's Name: _____ (please print)

Insured's ID#: _____

Insurance Company Name: _____

Insurance Company Address: _____

City: _____ State: ___ Zip: _____

Insurance Information *(check only one)*

- ☐ Uninsured
- ☐ Underinsured
- ☐ Insured, patient refuses to use
- ☐ Insured, clinic incapable of processing insurance
- ☐ Medicaid/Waiver information supplied

Facility Name: _____

Address: _____

City: _____ State: ___ Zip: _____

Enter your facility address
Results are returned
to this address

State Hygienic Laboratory
University of Iowa Research Park
2490 Crosspark Road, Coralville, IA 52241
Phone #: 319-335-4500
Fax #: 319-335-4555
http://www.shl.uiowa.edu

chlgc 122013

Specimen Collection and Transport

Package inserts with instructions for GEN-PROBE APTIMA Collection Kits – APTIMA Specimen Collection Guides are available upon request.

Female Endocervical Specimen Collection*

- Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in packaging with red printing). *Discard this swab!*
- Insert specimen collection swab (blue shaft swab in package with green printing) into the endocervical canal.
- Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
- Withdraw the swab carefully; avoid any contact with vaginal mucosa.
- Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- Carefully break swab shaft at score line; use care to avoid splashing contents.
- Re-cap swab specimen transport tube tightly.

Male Urethra Swab Collection*

Client should not have urinated for <u>at least</u> 1 hour prior to specimen collection.

- Insert specimen collection swab (blue shaft swab in package with green printing) 2 to 4 cm into the urethra.
- Gently rotate the swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling.
- Withdraw the swab carefully.
- Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- Carefully break swab shaft at score line; use care to avoid splashing contents.
- Re-cap swab specimen transport tube tightly.

Urine Specimen Collection (Male or Female) **

Client should not have urinated for <u>at least</u> 1 hour prior to specimen collection

- Direct client to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup, free from any preservatives. Collection of larger volumes may result in specimen dilution that may reduce test sensitivity. **Female clients should not cleanse labia area prior to providing specimen.**
- Remove cap from urine specimen transport tube, and transfer 2 mL of urine into urine specimen transport tube using disposable pipette provided. **The correct volume has been added when fluid level is between black fill lines on urine specimen transport tube label.** (This level is very important!)
- Re-cap urine specimen transport tube tightly. This is now known as the "processed urine specimen."

Vaginal Specimen Collection* (Non-pregnant women 16 years of age and older)

Specimen must be collected in a clinical setting. The specimen may be clinician or client (self) collected. Self- collected vaginal specimens are an option for screening asymptomatic women. The following instructions are for self-collected swabs. Clients must read the Patient Collection Instructions before providing them with a collection kit. For clinician-collected specimens, the vaginal specimen should be collected before inserting a speculum if an exam is to occur.

- Wash hands before starting.
- Partially peel open swab package. *Do not touch soft tip or lay swab down. If soft tip is touched, swab is laid down, or swab is dropped, request a new APTIMA Vaginal Swab Specimen Collection Kit.*
- Remove swab.
- Hold swab by placing thumb and forefinger in the middle of the swab shaft.
- Carefully insert swab into the inside opening of the vagina, about two inches and gently rotate swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
- Withdraw the swab without touching skin.
- While holding swab in the same hand, unscrew the tube cap. *Do not spill tube contents. If tube contents spill, request a new collection kit.*
- Immediately place swab into the transport tube so the tip of the swab is visible below the tube label.
- Carefully break swab shaft against the top side of the tube.
- Re-cap swab specimen transport tube tightly.

Instructions for collecting oropharyngeal/rectal specimens can be found in Appendix D.

* Specimen transport and storage -- After collection, transport and store swab in swab specimen transport tube at 2^0C to 30^0C until tested. Specimens must be assayed with the GEN-PROBE APTIMA Assay for CT and/or GC within 60 days of collection. If longer storage is needed, freeze at -20^0C to -70^0C for up to 90 days after collection.

**Specimen transport and storage – After collection, transport and store the processed urine specimen in the GEN-PROBE APTIMA urine specimen transport tube at 2^0C to 30^0C until tested. Processed urine specimens should be assayed with the APTIMA Assay for CT and/or GC within 30 days of collection. If longer storage is needed, freeze at -20^0C to -70^0C for up to 90 days after collection.

Packaging and Shipment of Swab and Urine Specimens

- Label each specimen tube with client's name and/or unique identifier.
  - UNLABELED SPECIMENS WILL NOT BE TESTED
- A complete CT/GC Test Request Form must accompany each specimen.
- Be sure the lid is tightened on the transport tube.
- Use one biohazard bag per specimen.
- Wrap the specimen transport tube in the absorbent material provided and place into biohazard bag. Seal the biohazard bag. Do not use rubber bands!
- Check to make sure the test request form is completely filled out. Fold the test request form in half and place in the white plastic circular mailers. Up to four specimens can be placed in the white mailing tubes.
- When shipping a large number of specimens, a sturdy cardboard box can be used instead of the plastic mailers. This will save postage.
- Use the preaddressed label provided.
- Transport specimens to SHL as soon as possible after collection.
- Transport at 2^0C to 27^0C (room temperature).

Criteria for Rejection/Infractions for Specimen Collection and Transport

- Specimen unsuitable for testing due to the use of an improper swab. Do not use the white shafted cleaning swab for specimen collection.
- Specimen unsuitable for testing due to transport buffer or urine leaked during transit. The transport tube cap was not securely tightened prior to shipment.
- Specimen unsuitable for testing due to the swab transport tube was received without a swab.
- Specimen unsuitable for testing due to improper specimen. The GEN-PROBE APTIMA Combo 2 Assay is only valid for female endocervical or vaginal swabs, male urethral swabs, male/female urine, oropharyngeal swabs, or rectal swabs.
- Specimen unsuitable for testing due to the use of an improper specimen collection kit. Submit only the GEN-PROBE APTIMA Combo 2 Assay specimen collection system.
- Specimen unsuitable for testing due to the client's name on the transport tube does not correspond to the name on the test request form.
- Specimen unsuitable for testing. No client identification was on the transport tube.
- Specimen unsuitable for testing. The test request form was received without a specimen.
- Specimen unsuitable for testing. No test request form was received with the specimen.

- Specimen not tested due to the client not meeting the CBSS screening criteria.
- Specimen unsuitable for testing due to specimen in transport tube contains two swabs. (Be sure to dispose of the white shaft cleaning swab.)
- Specimen unsuitable for testing due to improper quantity of urine. The fluid level in the urine transport tube must fall between the two black indicator lines on the tube level.
- Specimen not tested. Swabs cut above the break point cannot be processed. Swabs must be broken off at the indicated break-point on the swab. Failure to do so can cause contamination in the clinic and at the laboratory.

Ordering Specimen Collection Supplies

Test kits, test request forms, and all other CT/GC supplies are to be ordered through the CBSS Coordinator or Administrative Assistant at:

Community-Based Screening Services
Family Planning Council of Iowa
108 – 3rd Street, Suite 220
Des Moines, IA 50309
Phone: 515-288-9028
cbornmueller@fpcouncil.com

Collection kits can include:

- Unisex swab kits, vaginal swab kits or urine kits
- Test request forms
- Biohazard bags
- Absorbent material
- White mailing tubes
- Mailing labels

Individual components may be ordered separately. Swab and urine kits come in boxes of 50. You may specify a quantity less than 50, but only in lots of 50 if ordering more (e.g., 50, 100, 150, etc.) The order is forwarded to SHL.

- Order well in advance, before you run out of supplies. It can take up to 10 to 14 days to receive your test kits.
- It is important to avoid having test kits expire. Be sure to rotate stock of test kits often, watching expiration dates. Practice "First in – First out" policy.
- Supply orders should be based on an approximate supply for a 3-month time period. (Except in the case of urine test kits – the limit is 100 per order.)
- Forms are pre-printed with the clinic name and address. Please check the name and address at the bottom of the test request forms when you receive them. If the form is not correct, the client test results will be sent to the wrong clinic.

3. Test Results and Treatment Information

Receiving Test Results from SHL

SHL now offers chlamydia and gonorrhea test results via the web on the Public Health Information Management System (PHIMS). Test results are available as soon as they are completed and released, improving turn-around time. Results are in a printable format resembling reports that are mailed. Providers can check the status and the date specimens were received at SHL. Up to three individuals at each clinic site may sign up and receive a password to gain access to the results. Once the staff has completed training and becomes comfortable with the system, a separate request should be submitted to go "paperless." (The results will no longer be mailed.) SHL should be notified immediately if a staff person leaves the clinic so that access is terminated. Registration/enrollment forms can be found in Appendix B.

A full description of the Web Access Reporting System is found at:
http://www.shl.uiowa.edu/kitsquotesforms/phimswebaccessbrochure.pdf

Questions regarding test results should be directed to:

- Kris Eveland at kristofer-eveland@uiowa.edu or
- Jeff Benfer at jeff-benfer@uiowa.edu
  If it is not possible to email, you may call them at 319-335-4500.

Receiving Test Results in the Clinic

- As soon as a positive test result is received, it should be placed in the medical record.

Contacting the Client

- An attempt to contact the client should be made within 24 hours of receiving a positive test result and must be done within 3 working days.
- Each attempt to contact the client should be recorded in the medical record.
- When permissible, the first attempt to contact the client should be made by telephone. A physician, physician's assistant, nurse, nurse practitioner, or an appropriately trained non-medical person should make this call.
- Medical information is confidential, and the client should be reminded of this. Due to confidentiality, if the client is not home, ask that the phone call be returned. Do not give out medical information to anyone but the client.
- The client should be alerted to the serious nature of the infection and reminded that medical attention is needed immediately. Explain to the client that the infection is

easily treated and long-term consequences can be avoided if medication is received in a timely manner.

- Make an appointment with the client for counseling and treatment as soon as possible.
- If there is no way to contact the client by telephone, or attempts at telephone contact have been unsuccessful, a certified letter with a return request should be sent to the client.
- This letter should not contain alarming language. The confidential nature of the content must not be revealed. The letter should encourage the client to call with questions. The letter should state that this is the last attempt to contact the client.
- If the clinic is unable to contact a client with a positive chlamydia or gonorrhea test result, the state or local sexually transmitted disease program must be notified. State and local DPS help locate and contact clients. As staff of state or county public health departments, they have the right to client information related to reportable infections like chlamydia or gonorrhea. For the name of the DPS for your area go to http://www.idph.state.ia.us/IDPHChannelsService/file.ashx?file=4AB90493-4617-46A6-A89D-88E1BF53EF7B
- Treatment drugs for chlamydia and gonorrhea are available for all CBSS providers through IDPH. For enrollment and ordering information, contact the STD Program Manager at 515-281-4936.

Management of Sex Partners and Follow-up

- A partner referral system for assuring the examination and treatment of sex partners must be in place.
- Clients should be instructed to refer sex partners for evaluation, testing, and treatment.
    - Notification and referral can be accomplished in any of three ways:
        - By the client
        - By the clinic or provider
        - By the state or local DPS (**Please note:** Due to the high volume of cases, clients diagnosed with chlamydia will only be offered partner services/referral upon clinician request to your local DPS or the IDPH STD Program.)
- Sex partners should be evaluated and treated if they had sexual contact with the client during the 60 days preceding onset of symptoms or the diagnosis of chlamydia or gonorrhea.
- The most recent sex partner should be evaluated and treated even if the time of the last sexual contact was greater than 60 days before symptoms or diagnosis.
- A rescreen in three months is recommended for all individuals testing positive for chlamydia to check for new infection. If not seen within three months, retest those who present for care within 12 months.

Treatment of Chlamydia

Persons treated for chlamydia should be instructed to abstain from sexual intercourse for 7 days after single-dose therapy or until completion of a 7-day regimen.

Recommended

- Azithromycin 1 gram orally single dose, directly observed OR
- Doxycycline 100 mg. orally 2 times a day for 7 days

Alternative

- Erythromycin base 500 mg. orally 4 times a day for 7 days OR
- Erythromycin ethylsuccinate 800 mg. orally 4 times a day for 7 days OR
- Levofloxacin 500 mg. orally once a day for 7 days OR
- Ofloxacin 300 mg. orally 2 times a day for 7 days

Pregnant Females - Recommended

- Azithromycin 1 gram orally single dose, directly observed OR
- Amoxicillin 500 mg orally 3 times a day for 7 days

Pregnant Females – Alternative

- Erythromycin base 500 mg. orally 4 times a day for 7 days OR
- Erythromycin 250 mg orally 4 times a day for 14 days OR
- Erythromycin ethylsuccinate 800 mg. orally 4 times a day for 7 days OR
- Erythromycin ethylsuccinate 400 mg. 4 times a day for 14 days

You should counsel patients to abstain during treatment, use barriers and contraception for prevention, and to rescreen in 3 – 4 months.

You are **strongly encouraged** to read the complete current CDC Sexually Transmitted Diseases Treatment Guidelines for more detailed findings regarding screening, treatment and follow-up of chlamydia. For more information on the treatment guidelines, please visit www.cdc.gov/std/treatment

Treatment of Gonorrhea

Persons treated for gonorrhea should be instructed to abstain from sexual intercourse for 7 days after single-dose therapy or until completion of a 7-day regimen.

Recommended for uncomplicated urogenital, anorectal, and pharyngeal gonococcal infections

- Ceftriaxone 250 mg. IM in a single dose
  PLUS
- Azithromycin 1 gram orally in a single dose

See the CDC STD Treatment Guidelines for additional options if there are allergies or other concerns.

When treating using the recommended therapy, test-of-cure is unnecessary. Test-of-cure is only necessary when using one of the alternative regimens (e.g., cefixime) or when the patient meets one of the other criteria listed on page 16 of the *Cephalosporin-Resistant Neisseria gonorrhoeae Public Health Response Plan.*
http://www.cdc.gov/std/treatment/Ceph-R-ResponsePlanJuly30-2012.pdf

For test request forms and test-of cure kits call: 319/335-4500. For additional forms, go to http://www.shl.uiowa.edu/kitsquotesforms. Any questions pertaining to patient test results should be directed to the bacteriology section at 319-335-4448.

Gonorrhea Treatment Issues

- When a patient is diagnosed with gonorrhea, dual therapy for gonorrhea and chlamydia is required. Dual therapy slows the development of antimicrobial resistance and enhances oropharyngeal eradication. (Sathia 2007, Golden 2009)
- Suspected cephalosporin treatment failures should be cultured, and if positive:
  - Perform antimicrobial susceptibility testing
  - Consult a specialist for treatment guidance
  - Report case to CDC through state and local health departments
  - Health Department should prioritize partner notification
- The CDC website or the Iowa Department of Public Health can provide the most current information. SHL can also provide information regarding additional testing that may be needed.

Presumptive Treatment Criteria – Expedited Partner Therapy

- Presumptive treatment occurs before test results are available when a client presents with one or more complaints. Treatment may occur without actually testing the client.
- Criteria for presumptive diagnosis and treatment of chlamydia or gonorrhea:
    - Males
        - History of urethral discharge
        - History and/or exam consistent with urethritis, epididymitis, or non-gonococcal urethritis
        - History of sexual partner with chlamydial infection
        - History of sexual partner with gonococcal infection
        - Symptomatic partner
        - History of partner with mucopurulent cervicitis or PID
        - Rape victim
    - Females
        - Physical exam consistent with mucopurulent cervicitis, friable cervix or positive swab test
        - Signs or symptoms of PID
        - History of sexual partner with chlamydial infection
        - History of sexual partner with gonococcal infection
        - Symptomatic partner
        - History of partner with urethritis, epididymitis, or non-gonococcal urethritis
        - Rape victim

- Expedited Partner Treatment/Therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with chlamydia and/or gonorrhea by providing prescriptions or medications to the patient to take to his/her partner(s) without the health care provider first examining the partner(s). EPT can be accomplished in two ways. Patient- Delivered Partner Therapy (PDPT) occurs when a patient delivers the prescriptions or medications to her or his partner(s). Field-Delivered Therapy (FDT) is a practice that is similar to Directly Observed Therapy (DOT). FDT occurs when a public health professional, such as a Disease Prevention Specialist (DPS), delivers the prescription or medication to the partner(s).

- The gold standard for interrupting the transmission of sexually transmitted diseases (STDs) is to examine, test, and appropriately treat all sex partners of persons diagnosed with an STD. EPT has been demonstrated to be effective in accomplishing the last part of this standard. EPT is useful when partners are deemed unlikely to access health care themselves, and when a patient presents with re-infection(s).

The following is the Iowa code regarding EPT:

139A.41 CHLAMYDIA AND GONORRHEA Notwithstanding any other provision of law, a physician, physician assistant, or advanced registered nurse practitioner who diagnoses a sexually transmitted Chlamydia or Gonorrhea infection in an individual patient may prescribe, dispense, furnish, or otherwise provide prescription oral antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners. If the infected individual patient is unwilling or unable to deliver the medication to a sexual partner or partners, a physician, physician assistant, or advanced registered nurse practitioner may dispense, furnish, or otherwise provide the prescription oral antibiotic drug to the department or local disease prevention investigation staff for delivery to the partner or partners.

The instructions on how to use EPT in CBSS Provider Sites can be found on the IDPH website at: http://www.idph.state.ia.us/IDPHChannelsService/file.ashx?file=CDA25C68-F6DA-4471-8C1C-016C2CA44C81

State Reporting Requirements – Chlamydia and Gonorrhea

Iowa is a dual reporting state. **Both the clinician that diagnoses the infection and the laboratory that processes the specimen are required to report each event of a reportable infection to IDPH.** The following information offers guidance on how to report infections, including the timeframe in which they must be reported.

For STD infections, clinicians and laboratories must report each event of infection within three days of a positive test result. Iowa code 139A.32 states that a person in charge of a public, private, or hospital clinical laboratory shall report "all specimens which *yield evidence of or are reactive for* those diseases defined as sexually transmitted diseases or infections." The reportable STDs in Iowa are chlamydia, gonorrhea, syphilis, and HIV.

- Chlamydia
    - Confirmed positive results on any qualitative polymerase chain reaction (PCR) test, nucleic acid amplification test (NAAT), nucleic acid hybridization (DNA probe) test, enzyme-linked immunosorbent assay (ELISA, EIA), direct fluorescent antibody test (DFA), or culture.
- Gonorrhea
    - Confirmed positive results on any qualitative polymerase chain reaction (PCR) test, nucleic acid amplification test (NAAT), nucleic acid hybridization (DNA probe) test, enzyme-linked immunosorbent assay (ELISA, EIA), bacterial culture, or Gram stain. (Gram stain is only valid as a confirmatory test on urethral specimens from symptomatic males).

- Syphilis
    - Confirmed positive results by a treponemal test (e.g. TPPA, FTA, and IgG). The non-treponemal test (e.g., RPR or VDRL), with a quantitative titer, must also be reported.
        - Only report the set of labs (RPR/VDRL + TPPA/FTA) when the TPPA/FTA is positive. You do not need to report reactive RPRs when the TPPA is negative. However, when the TPPA is positive, please report the RPR no matter whether it is reactive or not. If a TPPA/FTA is not run, then report positive RPR/VDRL by itself.

The following section of *Iowa Administrative Code 641* describes what must be included in each event reported to the Iowa Department of Public Health:

641 – 1.4(2) ***What to report.*** Each report shall contain all of the following information:
a. The patient's name.
b. The patient's address.
c. The patient's date of birth.
d. The sex of the patient.
e. The race and ethnicity of the patient.
f. The patient's marital status.
g. The patient's telephone number.
h. The name and address of the laboratory.
i. The date the test was found to be positive and the collection date.
j. The name and address of the health care provider who performed the test
k. If the patient is female, whether the patient is pregnant.
l. The name of the reportable disease.

STD reporting forms can be ordered on line from the Clearinghouse at http://healthclrhouse.drugfreeinfo.org/cart.php?target=category&category_id=303 and following the ordering instructions. Postage-paid envelopes to mail the reporting forms to IDPH may be ordered from the Clearinghouse as well. Alternatively, you may call the IDPH STD Program at 515-281-30103 or 515-281-4936 to have a PDF of the most up-to-date reporting form emailed or faxed to you.

There is additional information and resources regarding STDs and for further client referrals in Appendix C.

4. Post-Test and Certification

All staff involved with the CBSS should review this manual and take the post-test included here. New staff, within 30 days of hire, should also read the manual and complete the test. A copy of the post-test is included here which you can complete and send to the CBSS Coordinator. Alternatively, the survey can be accessed and completed on Survey Monkey at http://www.surveymonkey.com/s/cbssposttest2014

A completion certificate will be mailed to the participants when a passing grade of 70% is achieved.

Community-Based Screening Services Manual Certification

Completing the Community-Based Screening Services post-test verifies that I have read and understand the Iowa Community-Based Screening Services Procedures Manual. I have included the post-test and I will be notified of the results. If I receive a passing grade of 70% or above, I will receive a Certificate of Participation.

Name _____

Clinic Name _____

Clinic Street Address_____

Clinic City, State, and Zip code_____

Email address _____

Please choose one:

- ☐ LPN
- ☐ RN
- ☐ CMA
- ☐ Nurse Practitioner
- ☐ Physician (MD or DO)
- ☐ Physician's Assistant
- ☐ Other _____

_____
Signature

_____
Date

Please return to:
Colleen Bornmueller, CBSS Coordinator
Family Planning Council of Iowa
108 3rd Street, Suite 220
Des Moines, IA 50309
Fax: 515-288-4048
cbornmueller@fpcouncil.com

CBSS Manual Post Test

Name_____

Please circle the correct answer for each question based on this manual. Choose only one answer per question. **You may also take this post-test online at Survey Monkey** http://www.surveymonkey.com/s/cbssposttest2014

1. According to the CDC, what is the percentage of chlamydia infections in women that are asymptomatic?
    a. 30%
    b. 50%
    c. 70%
    d. 100%

2. Optimal specimen collection types when using Nucleic Acid Amplified Testing (NAATs) for men are first catch urine and vaginal swabs for women.
    a. True
    b. False

3. Which program element will be addressed during a CBSS Facility Assessment site visit?
    a. Specimen collection and submission
    b. Screening Criteria
    c. Client/Partner treatment and education
    d. All of the above

4. New CBSS screening criteria apply to both male and female clients.
    a. True
    b. False

5. What must be considered first when deciding to use a CBSS test kit for specimen collection?
    a. Age
    b. Sexual orientation
    c. Insurance status
    d. Multiple partners

6. For clients 26 years of age and older, which of the following would **not** be considered a risk factor and qualify for the use of a CBSS test kit:
    a. Multiple partners in the last 90 days
    b. One new partner in the last year
    c. Contact with another individual that was diagnosed with an STD
    d. Symptoms reported by the patient

7. Gen-Probe APTIMA Combo 2 Unisex test kits are used to collect oropharyngeal and rectal specimens.
    a. True
    b. False

8. Which of the following reasons could cause SHL to reject and not process a specimen?
    a. Specimen unsuitable for testing due to the use of an improper swab.
    b. Specimen unsuitable for testing due to transport buffer or urine leaked during transit.
    c. Specimen unsuitable for testing due to the client's name on the transport tube does not correspond to the name on the test request form.
    d. All of the above

9. What is the only recommended treatment regimen for a diagnosed uncomplicated gonorrhea infection?
    a. Doxycycline 100 mg. orally, 2 times a day for 7 days
    b. Ceftriaxone 250 mg IM, single dose
    c. Azithromycin, 1 gram orally, single dose
    d. Ceftriaxone 250 mg IM, single dose plus Azithromycin 1 gram orally, single dose.

10. For STD infections, laboratories and clinicians must report each event of infection within how many days of a positive test result?
    a. 3 days
    b. 4 days
    c. 7 days
    d. 10 days

11. If the clinic or provider is not able to contact a client and he or she has not returned to the clinic for treatment, who should be contacted?
    a. The emergency room at a local hospital
    b. Another clinician
    c. The partner of the infected individual
    d. The state or local sexually transmitted disease program (e.g., DPS)

12. Expedited Partner Therapy (EPT) is the clinical practice of treating the sex partner(s) of patients diagnosed with chlamydia and/or gonorrhea by providing prescriptions or medications to the patient to take to his or her partner(s) without the health care provider first examining the partner(s).
    a. True
    b. False

Appendices

- Appendix A – Gen-probe APTIMA Sensitivity/Specificity Charts
- Appendix B - Web Access Registration Forms – Registration and Paperless
- Appendix C – Additional Resources and Contact Information
- Appendix D – Oropharyngeal and Rectal Specimen Collection Instructions and Screening Recommendations

C. trachomatis *Sensitivity and Specificity*

APTIMA Combo 2 Assay Specimens vs. Patient Infected Status

Specimen	Symptoms Status	N	TP	FP	TN	FN	Sensitivity (95% C.I.)	Specificity (95% C.I.)
MS	Symp	676	190	15	464	7	96.4% (92.8-98.6)	96.9% (94.9-98.2)
	Asymp	388	70	5	309	4	94.6% (86.7-98.5)	98.4% (96.3-99.5)
	All	1065	260	20	774	11	95.9% (92.9-98.0)	97.5% (96.1-98.5)
MU	Symp	694	199	8	484	3	98.5% (95.7-99.7)	98.4% (96.8-99..3)
	Asymp	400	77	4	316	3	96.3% (89.4-99.2)	98.8% (96.8-99.7)
	All	1095	276	12	801	6	97.9% (95.4-99.2)	98.5% (97.4-99.2)
FS	Symp	819	133	22	653	11	92.4% (86.7-96.1)	96.7% (95.1-97.9)
	Asymp	569	61	6	501	1	98.4% (91.3-100)	98.8% (97.4-99.6)
	All	1389	195	28	1154	12	94.2% (90.1-97.0)	97.6% (96.6-98.4)
FU	Symp	821	136	8	668	9	93.8% (88.5-97.1)	98.8% (97.7-99.5)
	Asymp	569	60	5	502	2	96.8% (88.8-99.6)	99.0% (97.7-99.7)
	All	1391	197	13	1170	11	94.7% (90.7-97.3)	98.9% (98.1-99.4)
Total Swab	Symp	1495	323	37	1117	18	94.7% (91.8-96..8)	96.8% (95.6-97.7)
	Asymp	957	131	11	810	5	96.3% (91.6-98.8)	98.7% (97.6-99.3)
	All	2454	455	48	1928	23	95.2% (92.9-96.9)	97.6% (96.8-98.2)
Total Urine	Symp	1515	335	16	1152	12	96.5% (94.0-98.2)	98.6% (97.8-99.2)
	Asymp	969	137	9	818	5	96.5% (92.0-98.8)	98.9% (97.9-99.5)
	All	2486	473	25	1971	17	96.5% (94.5-98.0)	98.7% (98.2-99.2)

N=Negative; TP= True Positive; FP= False Positive; TN=True Negative; FN= False Negative
MS= male Urethral Swab; MU= Male Urine; FS= Female Endocervical Swab; FU= Female Urine

Specimen	Symptom Status	N	TP	FP[1]	TN	FN	Sensitivity (95% C.I.)	Specificity (95% C.I.)
PVS	Asymp	628	60	18[a]	549	1	98.4% (91.2–100)	96.8% (95.0–98.1)
	All	1423	168	32[b]	1217	6	96.6% (92.6–98.7)	97.4% (96.4–98.2)
CVS	Symp	809	111	25[c]	669	4	96.5% (91.3–99.0)	96.4% (94.7–97.7)
	Asymp	636	59	16[d]	559	2	96.7% (88.7–99.6)	97.2% (95.5–98.4)
	All	1445	170	41[e]	1228	6	96.6% (92.7–98.7)	96.8% (95.6–97.7)

N = Negative; TP = True Positive; FP = False Positive; TN = True Negative; FN = False Negative.
PVS = Asymptomatic Patient-Collected Vaginal Swab; CVS = Clinician-Collected Vaginal Swab.
[1] CT TMA Alternate Amplification results represent # positive results/# specimens tested: a: 15/18, b: 28/32, c: 17/25, d: 15/16, and e: 32/41.

N. gonorrhoeae *Sensitivity and Specificity*

APTIMA Combo 2 Assay Specimens vs. Patient Infected Status

Specimen	Symptoms Status	N	TP	FP	TN	FN	Sensitivity (95% C.I.)	Specificity (95% C.I.)
MS	Symp	724	304	5	412	3	99.0% (97.2-99.8)	98.8% (97.2-99.6)
	Asymp	378	15	12	351	0	100% (78.2-100)	96.7% (94.3-98.3)
	All	1103	319	17	764	3	99.1% (97.3-99.8)	97.8% (96.5-98.7)
MU	Symp	750	311	1	433	5	98.4% (96.3-99.5)	99.8% (98.7-100)
	Asymp	383	13	2	368	0	100% (75.3-100)	99.5% (98.1-99.9)
	All	1134	324	3	802	5	98.5% (96.5-99.5)	99.6% (98.9-99.9)
FS	Symp	881	94	15	772	0	100% (96.2-100)	98.1% (96.9-98.9)
	Asymp	596	31	2	562	1	96.9% (83.8-99.9)	99.6% (98.7-99.9)
	All	1479	126	17	1335	1	99.2% (95.7-100)	98.7% (98.0-99.3)
FU	Symp	883	87	7	782	7	92.6% (85.3-97.0)	99.1% (98.2-99.6)
	Asymp	599	28	3	564	4	87.5% (71.0-96.5)	99.5% (98.5-99.9)
	All	1484	116	10	1347	11	91.3% (85.0-95.6)	99.3% (98.6-99.6)
Total Swab	Symp	1605	398	20	1184	3	99.3% (97.8-99.8)	98.3% (97.4-99.0)
	Asymp	974	46	14	913	1	97.9% (88.7-99.9)	98.5% (97.5-99.2)
	All	2582	445	34	2099	4	99.1% (97.7-99.8)	98.4% (97.8-99.2)
Total Urine	Symp	1633	398	8	1215	12	97.1% (94.9-98.5)	99.3% (98.7-99.7)
	Asymp	982	41	5	932	4	91.1% (78.8-97.5)	99.5% (98.8-99.8)
	All	2618	440	13	2149	16	96.5% (94.4-98.0)	99.4% (99.0-99.7)

N=Negative; TP= True Positive; FP= False Positive; TN=True Negative; FN= False Negative
.MS= male Urethral Swab; MU= Male Urine; FS= Female Endocervical Swab; FU= Female Urine

Specimen	Symptom Status	N	TP	FP[1]	TN	FN	Sensitivity (95% C.I.)	Specificity (95% C.I.)
PVS	Asymp	629	21	3a	605	0	100% (83.9–100)	99.5% (98.6–99.9)
	All	1423	74	8b	1341	0	100% (95.1–100)	99.4% (98.8–99.7)
CVS	Symp	807	51	7c	747	2	96.2% (87.0–99.5)	99.1% (98.1–99.6)
	Asymp	637	21	4d	611	1	95.5% (77.2–99.9)	99.3% (98.3–99.8)
	All	1444	72	11e	1358	3	96.05 (88.8–99.2)	99.2% (98.6–99.6)

N = Negative; TP = True Positive; FP = False Positive; TN = True Negative; FN = False Negative.
PVS = Asymptomatic Patient-Collected Vaginal Swab; CVS = Clinician-Collected Vaginal Swab
[1] GC TMA Alternate Amplification results represents # positive results/# specimens tested: a: 3/3, b: 8/8, c: 6/7, d: 3/4, and e: 9/11

Data Access Application for the State Hygienic Laboratory

Individuals requiring access to data must submit an application for authorization by the SHL. The SHL will issue a user ID and password for each individual upon approval of this application. By submitting this application, you acknowledge that you have read, understood, and agree to the Terms of Use specified below and on our web site at http://www.shl.uiowa.edu. This application must be filled in its entirety in order for the request to be processed. Please keep a copy of this application for your records. *Please type or print the requested information.*

Return this application form to:

State Hygienic Laboratory – Web Access
University of Iowa Research Park
2490 Crosspark Road
Coralville, Iowa 52241-4721
Phone: 319-335-4358
Fax: 319-335-4555
E-Mail: ask-shl@uiowa.edu

For further information, please contact Web Access. You may e-mail, fax, or mail this application.

Terms of Use

(1) SHL will make all reasonable efforts to ensure the accuracy of the information provided through this service, but will not be held liable for errors and/or omissions of any content.
(2) Tampering, reverse engineering or unlawful use of the content is strictly prohibited.
(3) When a user's access to data is to be discontinued, **it is the responsibility of the agency to notify the SHL 14 days prior to the date of termination of access for the said user**. Access will be removed within a reasonable amount of time of the request, but no later than the last day of allowed access.
(4) Initial passwords will be supplied by SHL. Users must change passwords as necessary but are responsible for the integrity and safe keeping of their password.
(5) Violation of said terms will result in immediate termination of access to SHL data, investigation, and possible legal action.

Organization Information

Organization Name: _____

Department: _____

Address1: _____

Address2: _____

City: _____ State: _____ Zip: _____

Applicant Information *(Required)*

First Name: _____ Email: _____

Middle Name: _____ Phone: (_____)_____-_____ ext. _____

Last Name: _____ Fax: (_____)_____-_____

Title: _____

By accessing and using our web site and these services, you acknowledge that you have read, understood, and agreed to the Terms of Use.

Signature of Applicant **Date**

Authorizing Representative Information *(Please complete if different from Applicant)*

First Name: _____ Email: _____

Middle Name: _____ Phone: (_____)_____-_____ ext. _____

Last Name: _____ Fax: (_____)_____-_____

Title: _____

Signature of Authorizing Representative **Date**

State Hygienic Laboratory

The University of Iowa

THE UNIVERSITY OF IOWA

Request for Paperless Result Delivery

Request for Paperless Result Delivery

You must have access to the SHL web reporting system BEFORE you can request paperless result delivery. If you would like access to the SHL web reporting system, please call Web Access at 319-335-4358 or e-mail ask-shl@uiowa.edu .

By submitting this form, you are agreeing to receive electronically available SHL laboratory test results by accessing the SHL Internet site. Test results available electronically will no longer be mailed.

To ensure legibility, please type or print clearly all requested information. Please print, sign, and fax the completed form to the State Hygienic Laboratory at 319-335-4555 or e-mail it to ask-shl@uiowa.edu .

Facility Information

Facility Name: _____

Address: _____

_____

City: _____ State: _____ Zip: _____

Phone: (_____) _____-_____ ext. _____

Authorizing Representative Information

Name: _____ Title: _____

Phone: (_____) _____-_____ ext. _____

Signature: _____ Date: _____

For questions or concerns, contact Web Access at 319-335-4358.

SHL USE ONLY

SHL Client # _____

State Hygienic Laboratory
University of Iowa Research Park
2490 Crosspark Road
Coralville, Iowa 52241-4721
(319) 335-4500 Fax: (319) 335-4555

http://www.shl.uiowa.edu

Ankeny Laboratory
2220 S. Ankeny Blvd.
Ankeny, IA 50023-9093
(515) 725-1600 Fax: (515) 725-1642

Additional Sources of Information

NATIONAL TELEPHONE HOTLINES AND TREATMENT LOCATORS

American Social Health Association's STI Resource Center
1-800-227-8922 or 919-361-8488
Talk to an information specialist 9 a.m. to 6 p.m. on Monday-Friday
919-361-4848
Pre-recorded telephone information messages 24/7

Emergency Contraception Hotline (NOT-2-LATE)
http://ec.princeton.edu/

Drug and Alcohol Treatment Locator
www.findtreatment.samhsa.gov

National Domestic Violence and Abuse Hotline
1-800-799-SAFE

National Gay and Lesbian Youth Hotline
1-800-347-TEEN

National Helpline Network
1-800-SUICIDE

SOURCES OF STD INFORMATION TO DISTRIBUTE TO PATIENTS

Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/std/chlamydia/
www2a.cdc.gov/nchstp_od/piweb/stdorderform.asp
The Centers for Disease Control and Prevention provides facts, statistics, and treatments options for patients with sexually transmitted infections.

America Social Health Association
www.ashastdwebstore.org
The American Social Health Association (ASHA) is a trusted, non-profit organization that has advocated on behalf of patients to help improve public health outcomes since 1914. ASHA offers high-quality patient education materials on a wide range of sexually transmitted infections.

Advocates for Youth
www.advocatesforyouth.org
Advocates for Youth was established in 1980 as the Center for Population Options. Their goal is to help young people make informed and responsible decisions about their

reproductive and sexual health. Advocates believes it can best serve the field by boldly advocating for a more positive and realistic approach to adolescent sexual health.

Get Yourself Tested Campaign
www.gytnow.org
The GYT campaign seeks to create a social movement around getting tested for STDs. Serving as the information hub for the campaign, www.GYTnow.org provides facts on STDs, tips on how to bring up testing with partners and health care providers, and an easy-to-use testing center locator, provided by the CDC.

Sexuality Information and Education Council of the United States
www.siecus.org
Sexuality Information and Education Council of the United States was founded in 1964 to provide education and information about sexuality and sexual and reproductive health. SIECUS educates, advocates, and informs.

GENERAL STD INFORMATION AND REFERRAL TO LOCAL CLINICS FOR SERVICES

http://hivtest.cdc.gov/STDTesting.aspx

CDC-INFO Contact Center
1-800-CDC-INFO (800-232-4636)
TTY: 1-888-232-6348, In English & en Español

CDC-INFO is available 24/7, 365 days a year for STD information and referrals to STD clinics

Oropharyngeal/Rectal Specimen Collection Instructions

Rectal Swabs

- Using the APTIMA Combo 2 Unisex Swab, insert specimen collection swab (blue shaft swab in package with green printing) into the rectum approximately 4-6 cm and rotate against rectal wall several times.
- Withdraw the swab carefully; avoid fecal contamination and in case of gross contamination discard the swab and recollect.
- Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- Carefully break swab shaft at score line; use care to avoid splashing contents.
- Re-cap swab specimen transport tube tightly.

Oropharyngeal Swabs

- Using a tongue depressor, if necessary, and the APTIMA Combo 2 Unisex Swab, insert specimen collection swab (blue shaft swab in package with green printing) into the pharynx and rotate against any inflammation and around the tonsillar area.
- Have the patient say “ah” for access to the pharynx and avoid touching the tongue, teeth, cheeks, etc. with the swab.
- Withdraw the swab carefully, again avoiding touching anything in the oral cavity.
- Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- Carefully break swab shaft at score line; use care to avoid splashing contents.
- Re-cap swab specimen transport tube tightly.

Testing Recommendations with Rectal/Pharyngeal Specimens

A sexual history of the patient must be taken in order to assess risk and determine the appropriateness of testing. **Please note: Oropharyngeal and rectal tests are subject to the same screening criteria established for urogenital specimens Please see the screening criteria and flow chart (page 9) first, in order to determine whether a patient is eligible for use of a CBSS test kit.**

Testing rectal specimens for gonorrhea and chlamydia is recommended when:

- The patient is MSM (man who has sex with men) and has had receptive anal intercourse within the past year, regardless of condom use.

Testing women for gonorrhea and chlamydia at the anorectal site is generally NOT recommended. Women should be screened at urogenital sites as previously recommended. Studies indicate that it is rare for a woman to be infected with gonorrhea or chlamydia *only* at the anorectal site. A very high percentage of women who have an anorectal gonococcal or chlamydial infection are also infected at urogenital sites; therefore gonorrhea and chlamydia will be detected when testing urogenital specimens. Furthermore, anorectal infections in women are not well correlated with reported history of anal intercourse.
Testing oropharyngeal specimens for gonorrhea* and is recommended when:

- The patient (male or female**) has performed oral intercourse on a man within the past year.
- The patient has performed oral intercourse on a partner who has tested positive for gonorrhea.

*According to CDC's STD Treatment Guidelines, 2010, "[Screening] for *Chlamydia trachomatis* pharyngeal infection is not recommended … The clinical significance and transmissibility of ***C. trachomatis*** detected at oropharyngeal sites is unclear, and the efficacy of different antibiotic regimens in resolving oropharyngeal chlamydia remains unknown." Because data on oropharyngeal chlamydia are very limited, this test should not be used for the purpose of screening patients for oropharyngeal chlamydial infection.

****Female patients with a history of multiple types of sexual intercourse**
If a patient reports a history of multiple types of sexual intercourse (e.g., vaginal, oral, or anal), collecting specimens from multiple sites is unnecessary and not recommended. Anytime a female patient reports vaginal intercourse *in addition* to other types of intercourse, only a urogenital specimen should be collected and screened for gonorrhea and chlamydia. There is no benefit to testing additional sites when the patient reports vaginal intercourse with her partner(s) because if the treatment guidelines are followed correctly, the medications used for urogenital infection will also eradicate the organism(s) from other body sites. Furthermore, *Neisseria gonorrhoeae* and *Chlamydia trachomatis* have the highest affinity for urogenital sites, therefore if a patient has engaged in multiple types of intercourse and been exposed to gonorrhea or chlamydia, a positive result will be obtained from the urogenital specimen.